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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|------------------------------|------------------------|
| 10/817,051 | 04/02/2004 | Gary P. Goodfried | DEP5111NP | 2235 |
| 27777 | 7590 | 06/08/2007 | | |
| PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 | | | EXAMINER RAMANA, ANURADHA | |
| | | | ART UNIT 3733 | PAPER NUMBER |
| | | | MAIL DATE 06/08/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|-----------------|------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/817,051 | GOODFRIED ET AL. | |
| | Examiner | Art Unit | |
| | Anu Ramana | 3733 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,9 and 26-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-8 and 10-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/15/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicants' election without traverse of Species I (Figs. 1-2) in the response filed on April 26, 2007 is noted. Accordingly, claims 1-2, 5-8 and 10-25 have been examined on the merits in this action and claims 3-4, 9 and 26-34 are withdrawn from further consideration since they are directed to non-elected species.

Drawings

The drawings are objected to because some of the figures appear to be copies of originals due to heavy shading (for e.g. Figs. 32 and 33). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement-drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The limitation, "at least 10 steps" has no upper limit.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5-7, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Neil et al. (US 6,071,311).

O'Neil et al. disclose a modular orthopedic implant system including: a first component 18 having a tapered bore 46 or 46' and an articulating surface; and a tapered metaphyseal component 14 including a first post 16 and a second post 20 wherein the two posts are different from each other in size and shape (Figs. 1, 3, 4, 7A-7B and 8B, col. 2, lines 60-67, cols. 3-6 and col. 7, lines 1-5).

Using an alternate interpretation, claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Neil et al. (US 6,071,311).

O'Neil et al. disclose a modular orthopedic implant system including: a first component 18 having a tapered bore 46 or 46' and an articulating surface; a tapered metaphyseal component 14; a first stem extension 12 and a second stem extension 20; and an adapter 16 having an end sized and shaped to be received in and mate with the opening of the tapered metaphyseal component and the opposite end of the adapter

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having an opening sized and shaped to receive and mate with the second femoral stem extension (Fig. 7B and col. 6, lines 37-65).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-14 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Neil et al. (US 6,071,311) in view of Bolesky (US 4,822,366).

O'Neil et al. disclose metaphyseal component 14 to have a plurality of steps 29 (col. 3, lines 1-16). See previous discussion of O'Neil et al.

Regarding claim 19, O'Neil et al. disclose a plurality of orthopedic components 12, 16 and 20 (Figs. 1, 3A, 4, 7A-7B and 8A-8B).

O'Neil et al. disclose all elements of the claimed invention except for surface treatment to render the metaphyseal component 14 porous.

Bolesky teaches providing surface treatment to a femoral stem or "metaphyseal component" 16 to render the component porous to enhance bone ingrowth (Figs. 1 and 11 and col. 5, lines 37-51).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have treated the O'Neil et al. metaphyseal component to render it porous, as taught by Bolesky, to enhance bone ingrowth.

Regarding claim 11, the combination of O'Neil et al. and Bolesky discloses all elements of the claimed invention except for a specific percentage of the length of the metaphyseal component being porous. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have formed the metaphyseal component porous over 75% of its length, since it has been held that

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discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claims 15-18 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Neil et al. (US 6,071,311) and Bolesky (US 4,822,366), further in view of Noiles (US 4,846,839).

The combination of O'Neil et al. and Bolesky discloses all elements of the claimed invention except for: (1) the number of steps or the number of steps per inch; and (2) the claimed spacing between adjacent steps.

Noiles teaches providing texture to a prosthesis wherein the texture includes steps with spacing between shoulders of the steps between 0.5 and 5 mm so as to generally correspond to the observed spacing between the points of intersection of fibers of soft bone with hard bone (col. 2, lines 45-51, col. 5, lines 1-6 and col. 6, lines 41-61).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have adjusted the number of steps to arrive at the claimed number of steps or steps per inch, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR

June 6, 2007



ANURADHA RAMANA
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